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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Mahenthiralingam Application No.: 09/763,298 Filed: 1/20/2001 Title: Method for the Identification and Speciation of Bacteria of the Burkholderia Cepacia Complex Attorney Docket No.: UBC.P-017	Group Art Unit: 1634 Examiner: M. Sheinberg

Assistant Commissioner for Patents

Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Restriction Requirement mailed November 4, 2002 for the above-captioned application, Applicants hereby elect the subject matter of Group I, Claims 1-7 with traverse. Reconsideration of the restriction requirement to the extent it separates the claims of Group I from those of Group II (Claims 8-12, 18 and 19) and Group III (Claims 13-16 and 20).

The present application is a PCT national phase, and is therefore governed by the provisions relating to Unity of Invention, rather than ordinary US restriction practice. In this case, Claims 1-7 relate to a method for identification and speciation of bacteria of the *Burkholderia sepacia* complex involving the determination of the sequence of the RecA gene.

I hereby certify that this paper and any attachments named herein are being deposited with the US Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on December 2, 2002.

Marina T. Larson

Marina T. Larson, PTO Reg. No. 32,038

December 2, 2002

Date of Signature

The method is can be carried out using genomovar specific primer pairs that have amplification specificity for different sequences in the RecA gene. The sample may be amplified prior to sequencing, in which case, two alternative sets of amplification primers, Seq 3 and 4, or Seq 20 and 21 are disclosed that can be used in practicing this method, and these primer pairs are recited in dependent claims. These primers are significant because they amplify a diagnostic portion of all of the known genomvars of the *B. cepacia* complex.

The claims of Group II are directed a composition comprising a pair of primers for amplification the RecA gene of *B. cepacia* complex. The specific primer pairs which meet this requirement are Seq 3 and 4, or Seq. 20 and 21, the same primer pairs specifically recited in the dependent claims of Group I. It is noted, however, that contrary to the Examiner position, as reflected in the request for a species election, that the primers define din this claim do not bind to any one of the identified sequences, they bind to all of them, such that these amplification primers are not genomovar specific.

The claims of Group III are directed to genomovar-specific primers which are used which are used to determine the type of *B. cepacia* present in the sample.

The Examiner asserts that the claims groups lack unity of invention, because they lack the same special technical feature. In making this argument, however, the Examiner has been overly specific, and defined the technical feature in the specific sequences, and said that if these sequences are not **required** by the independent method claim then there is a lack of unity. Applicants submit that this position does not comply with PCT and Unity of Invention Practice. For example, Example 4 of Appendix B of the PCT Administrative guidelines, reads a follows:

> Claim 1 Use of a family of compounds X as insecticides.
>
> Claim 2 Compound X_1 belonging to family X.
>
> Provided X_1 has the insecticidal activity and the special technical feature in claim 1 is the insecticidal use, unity is present.

X_1 is not required for use in claim 1, which is broader in its definition of the compound, yet there is unity of invention. Similarly, Example 16 shows the same thing:

> Claim 1 An insecticide composition comprising compound A (consisting of a 1, a 2...) and a carrier.
>
> Claim 2 Compound a_1.

> All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance. There is nevertheless still unity between the subject matter of claims 1 and 2 provided a 1 has the insecticidal activity which is also the special technical feature for compound A in claim 1.

In this case, the special technical feature of the claims of Group I is genomovar typing of *B. cepacia* based on sequence difference in the RecA gene. The compositions and kits defined in Group II are *B. cepacia* Rec A amplification primers which do not discriminate between genomovars. Thus, while they do not encompass every amplification primer which might be used in the method of the Group I claims, they do represent a preferred set of amplification primer pairs which are specifically adapted for use in the method of the claims when pre-amplification is performed.

The primer pairs of Group III are genomovar specific primer pairs which can be used to create diagnostic amplification products from a sample containing *B cepacia* bacteria. Thus, these primers are specifically adapted for carrying out the method of the invention (although there are other ways it could be done such as direct sequencing) because they all result in "obtaining nucleotide sequence information for the RecA gene as provided for in step (a) of claim 1.

Applicants submit that in view of the foregoing, that there isUnity of Invention with respect to the claims of Groups I-III which are intimately interwoven both in composition and in intended use. Applicants further point out that the International Searching Authority found that all of claims 1-16 shared Unity of Invention because the reagents claims were for use in the methods of claims 1-7. Thus, the restriction requirement with respect to Groups I-III should be withdrawn.

With respect to the request for designation of species, Applicant notes that the Examiner cites 37 CFR § 1.143 as authority for this requirement. Section 1896 of the MPEP states with respect to Unity of Invention Practice that

> U.S. national applications filed under 35 U.S.C. 111(a) are subject to restriction practice in accordance with 37 CFR 1.141-1.146. See MPEP § 803. U.S. national stage applications filed under 35 U.S.C. 371 are subject to unity of invention practice in accordance with 37 CFR 1.475 and 1.499 (effective May 1, 1993).

37 CFR § 1.143 is not indicated as applicable to National Stage applications and § 1.499 says nothing about species elections. Ths, this requirement is traversed. Nevertheless, Applicants

note the following. If it is more convenient, the Examiner may start the Examination process with the sequences 3 and 4 as the non-specific amplification primers, and with sequence 22 and 23 as the genomovar specific primer pair. With respect to the assertion that an election is necessary as between which of sequences 1, 2 and 5-19 the non-specific amplification primers of Group II bind to, Applicant submits that this is inappropriate because claim 8 requires primers that bind to **each**, i.e. all of these sequences, and not just to any one.

For the foregoing reasons, Applicants submit that the claims of Groups I, II and III should be examined in this application.

Respectfully Submitted,

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